Michael A. Caddell (SBN 249469)
mac@caddellchapman.com
Cynthia B. Chapman (SBN 164471)
cbc@caddellchapman.com
Amy E. Tabor (SBN 297660)
aet@caddellchapman.com
CADDELL & CHAPMAN
628 East 9th Street
Houston TX 77007-1722
Tel.: (713) 751-0400
Fax: (713) 751-0906

Attorneys for Plaintiff

IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

EDWARD PEÑA, individually and on behalf of others similarly situated,

Plaintiff,

v.

INTERNATIONAL MEDICAL DEVICES, INC., MENOVA INTERNATIONAL, INC., GESIVA MEDICAL, LLC, JAMES J. ELIST M. D., a Medical Corporation, and Dr. James ELIST,

Defendants.

Case No. 2:22-cv-003391-SSS (PLAx)

JOINT RULE 26 REPORT

Date: July 21, 2023
Time: 1:00 p.m.
Ctrm: 2
Judge: Hon. Sunshine S. Sykes

Pursuant to Fed. R. Civ. P. 26(f), Central District of California Local Rule 26-1, and the Court's Order setting a scheduling conference in this action, (Dkt. 66), the parties file this Joint Rule 26 Report.

a. Statement of the Case

Plaintiff's Position: Plaintiff alleges that Defendants made false and misleading statements and omitted material facts in marketing the "Penuma" penile implant device and surgical procedure. Defendants market Penuma as being approved or cleared by the FDA, as resulting in a natural looking penis, and as being reversible. Plaintiff alleges that, contrary to these misrepresentations, Penuma was cleared only for cosmetic correction of deformities until May 13, 2022, and has never been FDA-approved following the FDA's testing and approval process for new medical devices. Also contrary to Defendants' representations, Penuma "causes disfigurement and scarring that often leads to a shortening of the erect penis in the majority of cases." (Dkt. 16 ¶ 62.) Common complications from Penuma include infection requiring removal of the Penuma device, which leads to further scarring and shortening of the penis. (*Id.* ¶¶ 62–65.)

Plaintiff brings his claims on his own behalf and on behalf of a Class of all individuals in the United States who purchased a Penuma device and implantation procedure and whose procedures were performed by Dr. James Elist at the Beverly Hills South Pacific Surgery Center from May 19, 2018, through the date of certification. Plaintiff brings claims under California's False Advertising Law, CAL. BUS. & PROF. CODE § 17500 ("FAL"), California's Consumer Legal Remedies Act, CAL. CIV. CODE § 1750 *et seq.* ("CLRA"), and California's Unfair Competition Law, CAL. BUS. & PROF. CODE § 17200 *et seq.* ("UCL"). Plaintiff seeks damages and restitution in the amount of the money he and the Class members paid for the Penuma device and implantation procedure. Plaintiff also seeks to enjoin Defendants from making further false and misleading statements regarding Penuma.

Defendants' Position: Defendants deny the allegations of the Complaint and that Plaintiff Edward Peña was damaged as a result of Defendants' actions. Defendants contend that the Penuma is FDA-cleared, and that Plaintiff Edward Peña was informed of the potential risks of the Penuma and procedure, including the potential for scarring, shortening of the penis, infection, and the potential need for removal of the Penuma. Defendants therefore deny that they made false or misleading statement or omissions in Penuma marketing and deny that they are liable under the FAL, CLRA, or UCL. Defendants further contend that Plaintiff cannot meet Rule 23's requirements for class certification and deny that Plaintiff is entitled to restitution or injunctive relief. Defendants reserve the right to assert other defenses as their investigation continues.

b. Subject Matter Jurisdiction

The Court has subject matter jurisdiction over this case pursuant to 28 U.S.C. § 1332 because this is a class action involving over 100 class members in which at least one member of the class is a citizen of a State different from at least one Defendant and the matter in controversy exceeds $5,000,000, exclusive of interest and costs.

c. Legal Issues

At this time, the principal legal issues that the parties dispute include the following:

1. Whether Defendants' Statements Regarding Penuma Were False and Misleading

Plaintiff's Position: Plaintiff's position is that Defendants' statements regarding Penuma are false and misleading because Defendants advertise Penuma as "the first FDA-cleared penile implant" without disclosing that it has been cleared only under Section 510(k) of the Food, Drug, and Cosmetic Act ("FDCA"), not tested or approved by the FDA, and that up until May 19, 2022, it was cleared only

for the "correction of soft-tissue deformities." Plaintiff also asserts that Defendants' marketing of Penuma as "natural looking" is false and misleading because many patients' penises have an unnatural or deformed appearance after the surgery. Plaintiff also asserts that Defendants' marketing of Penuma as causing no interference with normal penis function is false and misleading because many patients experience sexual dysfunction and a loss of sensation as a consequence of receiving the Penuma implant. In addition, Plaintiff asserts that Defendants' statement that the Penuma procedure is permanent but "reversible" is misleading because in fact removal of the Penuma device causes scarring and shortening of the penis and does not restore the penis to its pre-operative appearance.

Defendants' Position: Defendants deny that they made false or misleading statements about the Penuma. To the contrary, Plaintiff Edward Peña signed an informed consent acknowledging that he was informed of the potential risks detailed above, including sexual dysfunction, loss of sensation, scarring, shortening of the penis, "infection or erosion of [the Penuma] requiring removal," and that "removal of [the Penuma] may result in penile retraction, scar formation, and other potential complications." In addition, Defendants' statements about FDA's clearance of Penuma were and are factually correct—Penuma is FDA cleared. Notably, Plaintiff's position above regarding Penuma's FDA clearance is inconsistent with the allegations of the Original, First, and Second Amended Complaints.

2. Whether Plaintiff Reviewed and Relied Upon Any Defendants' Marketing Statements Regarding the Penuma.

Defendants' Position: An anticipated (and highly individualized) issue will be whether Plaintiff Edward Peña actually saw and reasonably relied upon any of the marketing statements discussed in the Second Amended Complaint.

Plaintiff's Position: Reliance may be decided on a class-wide basis because Defendants made material omissions of facts which they had a duty to disclose.

3. Whether Plaintiff Can Prove Facts to Establish Enterprise Liability

Defendants' Position: Given the disparate roles of each individual Defendant as to Penuma and the lack of profit sharing among Defendants, Defendants anticipate that a legal issue will be whether Plaintiff can prove facts sufficient to establish enterprise liability.

4. Plaintiff's Position: Defendants are under common ownership and acted in concert regarding the marketing of Penuma.Whether Plaintiff's Claims Are Barred by the Release of Claims

Defendants' Position: Defendants contend that Plaintiff Edward Peña's claims are barred by the Release of Claims he signed, agreeing to release Defendants from "any and all actions, causes of actions, claims, demands . . . foreseen and unforeseen . . . resulting from any acts or omissions of [Defendants]."

Plaintiff's Position: Plaintiff denies that he released any claims against Defendants.——

5. Whether a Class Should Be Certified

Plaintiff's Position: Plaintiff seeks certification of a Class including:

> All individuals in the United States, including its territories and the District of Columbia, who purchased a Penuma device and implantation procedure and whose procedures were performed by Dr. James Elist at the Beverly Hills South Pacific Surgery Center from May 19, 2018 through the date of certification.

Plaintiff will seek leave to amend to also seek certification of a Pre-May 13, 2022 Subclass comprising all Class members whose procedures were performed from May 19, 2018 to May 12, 2022. (Note that the Class Period for which Plaintiff intends to seek certification was set forth in Plaintiff's Original Complaint. Because of a scrivener's error, Plaintiff's counsel inadvertently omitted to change the date of the beginning of the Class Period from "four years before the filing of this

Complaint" to the actual date, May 19, 2018, in his First and Second Amended Complaints. Plaintiff will correct this error in his proposed Third Amended Complaint.)

Plaintiff's position is that common issues predominate and class certification is appropriate because Defendants consistently misrepresented Penuma in their marketing and advertising. If Plaintiff and the Class members had known the true facts regarding Penuma, including that it is not FDA approved and was not even cleared under Section 510(k) except for the correction of soft-tissue deformities up until May 13, 2022, that it often does not result in a natural-looking penis, that it often causes complications including infection, scarring, and a loss of sensation, and that it cannot be removed without causing further infection and scarring leading to a shortening and often permanent disfigurement of the penis, they would not have purchased the Penuma device and procedure.

Defendant's Position: Defendants note that the Class Definition set out above is an expansion from that set forth in the operative Second Amended Complaint, which sought to certify the following class:

> All individuals in the United States, including its territories and the District of Columbia, who purchased a Penuma device and implantation procedure and whose procedures were performed by Dr. James Elist at the Beverly Hills South Pacific Surgery Center **from four years prior to the filing of this complaint through the date of certification.**

The Second Amended Complaint was filed on January 20, 2023; four years prior to that date is January 20, 2019, not May 10, 2018. Defendants note that this expanded definition—along with the subclass discussed above—appears in the proposed Third Amended Complaint, which Plaintiff has not yet filed.

Defendants' Position is that the proposed class is not appropriate for certification, and Defendants intend to oppose any motion for class certification.

d. Parties and Evidence

Plaintiff's Position:

Parties:

Edward Peña – Plaintiff

International Medical Devices, Inc. – Defendant

Menova International, Inc. – Defendant

Gesiva Medical, LLC – Defendant

James J. Elist, M.D., a Medical Corporation – Defendant

Dr. James Elist – Defendant

Percipient Witnesses:

Edward Peña

Penuma Patient #1

Penuma Patient #2

Penuma Patient #3

Penuma Patient #4

Dr. James Elist

Jonathan Elist

Bryan [redacted]

Key Documents:

Dr. Elist's website at www.drelist.com and related websites and social media postings used by Defendants to market Penuma.

Articles from medical journals regarding results and complications of penile implant surgery.

Defendants' analyses of the safety and effectiveness of Penuma.

Letter from U.S. Food & Drug Administration to International Medical Devices, Inc. Re: K181387 Trade/Device Name Pre-Formed Penile Silicone Block (January 23, 2019) and other documents related to Penuma's FDA clearance.

Documents, photos, and videos from Edward Peña regarding his experience with Penuma.

Complaints to Defendants regarding complications and poor results of Penuma surgery.

The California Medical Board's Fifth Amended Accusation *In the Matter of the Fifth Amended Accusation Against James Jamshid Elist, M.D.*, No. 800-2018-048274 (March 8, 2023), *available at* https://www2.mbc.ca.gov/BreezePDL/document.aspx?path=%5CDIDOCS%5C20230308%5CDMRAAAJD3%5C&did=AAAJD230309001531190.DID accusing Dr. Elist of gross negligence, repeated negligent acts, and incompetence, and related documents.

Press articles containing alleged misrepresentations from Dr. Elist regarding Penuma, including Ava Kofman, *The Perils and Promises of Penis-Enlargement Surgery*, The New Yorker (June 26, 2023), *available at* https://www.propublica.org/article/penis-enlargement-enhancement-procedures-implants, and Abby Ellin, *The big short*, Insider (March 14, 2023), *available at* https://www.insider.com/penuma-implant-penis-enlargement-enhancement-surgery-james-elist-2023-3

Defendants' Position: The parties to the lawsuit are Plaintiff Edward Peña and Defendants International Medical Devices, Inc., Menova International, Inc., Gesiva Medical, LLC, James J. Elist, M.D., a Medical Corporation, and Dr. James Elist. The witnesses in this case will be Plaintiff Edward Peña, family members, friends, co-workers, roommates or cohabitants, and intimate partners of Plaintiff

Edward Peña, Dr. James Elist, Jonathan Elist, and Dr. Bryan Kansas. Key documents in this case include:

- Edward Peña Penuma Eligibility Questionnaire, June 15, 2020.
- Cancellation and Payment Policy, Acknowledged and Signed by Edward Peña, July 17, 2020.
- Patient Intake Form for Edward Peña.
- Release of Claims executed by Edward Peña, October 2, 2020.
- Consent for Elective Penile Enhancement Surgery executed by Edward Peña, October 2, 2020.
- Physician-Patient Arbitration Agreement executed by Edward Peña, October 2, 2020.
- Subcutaneous Soft Silicone Penile Implant Limited Lifetime Warranty executed by Edward Peña, October 2, 2020.
- Records of Edward Peña's October 2, 2020 Penuma surgery and treatment pre- and post-surgery.
- Penuma testimonial video featuring Edward Peña.
- Documents and communications with the United States Food and Drug Administration (FDA) regarding FDA-clearance for Penuma.
- Medical literature related to the Penuma implant and surgery.

For conflict purposes, Defendants International Medical Devices, Inc., Menova International, Inc., and James J. Elist, M.D., a Medical Corporation, are California corporations. No publicly held corporation owns 10% or more of their stock. Defendant Gesiva Medical, LLC is a Minnesota limited liability corporation. No publicly held corporation owns 10% or more of its stock.

e. Service of Complaint

Plaintiff has served the summons and complaint on all Defendants.

f. Damages

Plaintiff seeks restitution of the cost for purchase of the Penuma device and procedure, which ranges from approximately $14,000–20,000, on behalf of himself and all Class members. The Class is estimated to include thousands of patients. Defendants deny that Plaintiff is entitled to the damages sought and that the class is estimated to include thousands.

g. Insurance

Plaintiff's Position: In its initial disclosures, Defendant International Medical Devices, Inc. stated that it would produce a copy of an insurance agreement that may provide coverage in the event of a judgment in this case.

Defendant's Position: There is currently no insurance coverage for Plaintiff's claims.

h. Motions

Plaintiff plans to seek leave to amend his complaint to add a second proposed Class representative and to address an updated FDA Clearance that Defendant International Medical Devices, Inc. ("IMD") obtained on May 13, 2022.

i. Dispositive Motions

Plaintiff's Position: The Court has denied two Motions to Dismiss. (ECF Nos. 50, 61.) Plaintiff does not believe any remaining issues or claims may be determined by a motion to dismiss or motion for summary judgment.

Defendants' Position: Defendants currently anticipate a motion to dismiss allegations in Plaintiff's Third Amended Complaint should the Court permit amendment, as well as a Motion for Summary Judgment as to some or all of the legal issues noted above. In addition, defendants are evaluating a potential motion to

compel arbitration in light of the arbitration agreement, and have conferred about this with Plaintiff's counsel.

j. Manual for Complex Litigation

The parties agree that the procedures of the Manual for Complex Litigation regarding class actions should be utilized.

k. Status of Discovery

Plaintiff served his first set of Requests for Production, Interrogatories, and Requests for Admission on September 9, 2022. Defendants objected to answering this discovery on the grounds that a Rule 26(f) conference had not been held. After the parties met and conferred about this objection and held a preliminary Rule 26(f) conference, Defendants served written objections and responses to this discovery on May 11, 2023. The parties are in the process of discussing appropriate search terms for electronically stored information. Plaintiff anticipates there may be a dispute regarding whether Defendants will use search terms to find patient complaints, other than a small number of adverse event reports submitted to the FDA, regarding complications from Penuma. Defendants note that the parties are still in the process of meeting and conferring as to search terms, and that Defendants have received no deficiency letter relating to their discovery responses served nearly two months ago.

Defendant IMD served written discovery on Plaintiff on May 5, 2023. Plaintiff responded to this discovery on June 5, 2023.

The parties are meeting and conferring about the terms of a protective order to govern any confidential information that may be produced.

l. Discovery Plan:

(A) The parties exchanged initial disclosures on May 5, 2023.

(B) **Plaintiff's Position**: Plaintiff anticipates taking depositions pursuant to FED. R. CIV. P. 30(b)(1) and 30(b)(6) before filing his motion for class certification. Plaintiff anticipates taking further 30(b)(1) depositions of Defendant's employees

and an additional FED. R. CIV. P. 30(b)(6) deposition before trial. Plaintiff's discovery will concern Defendants' misrepresentations regarding Penuma, Defendants' knowledge of the falsity of these misrepresentations, patient complaints regarding Penuma, the identification of Class members, and the quantification of damages. Plaintiff also plans to designate at least one expert at the class certification stage and likely additional experts at the merits stage and to take the deposition(s) of any expert(s) designated by Defendant.

Plaintiff understands that the Court's Standing Order has stayed merits discovery and does not seek to take discovery on purely merits-related issues prior to class certification. In this case, however, many issues are relevant to both class certification and the merits. To support his motion for class certification, Plaintiff intends to develop evidence showing that a reasonable consumer would not have purchased Penuma knowing the true facts about its FDA approval status, results, and common complications. This evidence will overlap substantially with evidence on the merits.

Plaintiff proposes completing class certification discovery by November 20, 2023 and filing his motion for class certification by January 17, 2024. Following a hearing on class certification on or around April 19, 2024 (at the Court's convenience), Plaintiff proposes a further merits discovery period until Friday September 13, 2024.

Defendants' Position: Defendants anticipate that discovery may be necessary on issues related to standing, reliance, damages, and class certification. At this time, Defendants anticipate deposing Plaintiff Edward Peña regarding the materials he reviewed related to the Penuma and his surgery, including, but not limited to, the informed consent discussing potential risks of the procedure, the pre-surgery questionnaire he completed describing his penis as defective, and the release of claims he signed. Defendants also anticipate deposing Plaintiff Edward Peña's

family members, friends, and intimate partners regarding Mr. Peña's claims related to his penis, health and sexual habits both (pre and post-surgery) consistent with Mr. Peña's claims regarding his Penuma experience.

Defendants propose the discovery schedule set out in the attached Schedule and proposed additional dates, which sets forth a briefing schedule for dispositive motion practice on Plaintiff's anticipated Third Amended Complaint, followed by class discovery, class certification briefing, and merits discovery.

(C) The parties have agreed to produce electronic discovery with a loadfile containing the relevant metadata. The parties are meeting and conferring about search terms for electronically stored information.

(D) The parties have agreed to a protective order including a provision for the clawback of inadvertently disclosed privileged information pursuant to FED. R. EVID. 502.

(E) The parties do not propose any limitation or modification of the discovery rules at this time.

(F) The parties do not propose any other orders that the Court should issue under Rule 16(b) or (c).

m. Fact Discovery Cut-Off

Plaintiff proposes a merits fact discovery cut-off of September 13, 2024.

n. Expert Discovery

Plaintiff proposes that Plaintiff's class certification expert reports be produced by December 4, 2023; Defendant's class certification expert reports be produced by December 18, 2023; and rebuttal reports be exchanged by January 8, 2024.

Plaintiff further proposes that merits expert reports be produced by September 6, 2024 and rebuttals reports by September 20, 2024. Plaintiff proposes an expert discovery cut-off of October 18, 2024.

Defendants propose that Plaintiff's class certification expert reports be produced with Plaintiff's Motion for Class Certification by January 17, 2024, and that Defendants' class certification expert reports be produced with their Class Certification Response Brief by March 29, 2024.

Defendants further propose that the Parties' trial expert reports be produced by September 20, 2024.

o. Settlement Conference/Alternative Dispute Resolution ("ADR")

No settlement negotiations have occurred to date. The parties agree that private mediation would be the most appropriate ADR method.

p. Trial Estimate

The parties estimate that trial would take approximately 8–10 days. Plaintiffs anticipate calling approximately ten witnesses. Defendants anticipate calling approximately 5-7 witnesses. Trial will be to a jury. The length of the trial estimate is based on the complexity of the case and the anticipated need for expert testimony on medical issues and damages.

q. Trial Counsel

Michael A. Caddell will try the case for Plaintiff.

Michael Mallow will try the case for Defendants.

r. Independent Expert or Master

The parties do not believe appointment of an independent expert or master is appropriate.

s. Schedule Worksheet

Please see the attached Schedule Worksheet.

t. Class Actions

Plaintiff proposes that he should file his motion for class certification by January 17, 2024, that Defendant's response should be due February 28, 2024, and that his Reply should be due March 22, 2024.

Defendants propose that the motion for class certification and expert reports be filed by January 17, 2024, that Defendants' response and expert reports be filed by March 29, 2024; and that Plaintiff's reply be filed by May 14, 2024.

u. Other Issues

The parties are not aware of any other issues requiring the Court's attention at this time.

Dated: July 7, 2023

Respectfully submitted,

By: */s/ Michael A. Caddell*

Michael A. Caddell (SBN 249469)
mac@caddellchapman.com
Cynthia B. Chapman (SBN 164471)
cbc@caddellchapman.com
Amy E. Tabor (SBN 297660)
aet@caddellchapman.com
CADDELL & CHAPMAN
628 East 9th Street
Houston TX 77007-1722
Tel.: (713) 751-0400
Fax: (713) 751-0906

Attorneys for Plaintiff

CERTIFICATE OF SERVICE

I, Amy E. Tabor hereby certify that on July 7, 2023 this document was filed with the Court using the CM/ECF system and thereby served on all counsel of record.

/s/Amy E. Tabor
Amy E. Tabor